E 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 152

[EPA-HQ-OPP-2019-0701; FRL-7542-05-OCSPP]

RIN 2070-AK56

Pesticides; Addition of Chitosan (Including Chitosan Salts) to the List of Active Ingredients Permitted in Exempted Minimum Risk Pesticide Products

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is adding a substance commonly referred to as chitosan (also known by its chemical name: poly-D-glucosamine) (CAS No. 9012-76-4) to the list of active ingredients eligible for use in minimum risk pesticide products exempt from registration and other requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). In doing so, EPA is specifying that the listing also includes those chitosan salts that can be formed when chitosan is mixed with the acids that are listed as active or inert ingredients eligible for use in minimum risk pesticide products.

DATES: This final rule is effective on [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE ***Federal Register***].

ADDRESSES: The docket for this action, identified under docket identification (ID) number EPA-HQ-OPP-2019-0701, is available at *https://www.regulations.gov.* Additional instructions on visiting the docket, along with more information about dockets generally, is available at https://www.epa.gov/dockets.

FOR FURTHER INFORMATION CONTACT: Charles Smith, Director, Biopesticides and Pollution Prevention Division (7511M), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 566-2427; email address: *BPPDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You may be potentially affected by this action if you manufacture, distribute, sell, or use minimum risk pesticide products. Minimum risk pesticide products are exempt from registration and other FIFRA requirements and are described in 40 CFR 152.25(f). The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

• Pesticide and other agricultural chemical manufacturers (NAICS codes 325320 and 325311), as well as other manufacturers in similar industries such as animal feed (NAICS code 311119), cosmetics (NAICS code 325620), and soap and detergents (NAICS code 325611).

• Manufacturers who may also be distributors of these products, including farm supplies merchant wholesalers (NAICS code 424910), drug and druggists merchant wholesalers (NAICS code 424210).

• Retailers of minimum risk pesticide products, including nursery, garden center, and farm supply stores (NAICS code 444220); outdoor power equipment stores (NAICS code 444210); and supermarkets (NAICS code 445110).

• Users of minimum risk pesticide products, including the public in general, exterminating and pest control services (NAICS code 561710), landscaping services (NAICS code 561730), and sports and recreation institutions (NAICS code 611620). Many of these entities also manufacture minimum risk pesticide products.

B. What action is the Agency taking?

EPA is adding chitosan to the list of active ingredients allowed in minimum risk pesticide products exempt from registration and other requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq*. In addition, EPA is specifying that the listing

also includes those chitosan salts that can be formed with the acids that are listed as active or inert ingredients eligible for use in minimum risk pesticide products.

Chitosan is a naturally occurring substance found in the cell walls of many fungi. Chitosan also occurs in the shells of all crustaceans (e.g., crab, shrimp, and lobster) and in the exoskeletons of most insects. Microorganisms in nature produce enzymes that break down chitosan, resulting in sugars that are metabolized as a carbon and nitrogen source.

C. What is EPA's authority for taking this action?

This action is issued under the authority of FIFRA, 7 U.S.C. 136 *et seq*., particularly FIFRA sections 3 and 25.

D. Why is EPA taking this action?

EPA may exempt from the requirements of FIFRA any pesticide that is "…of a character which is unnecessary to be subject to [FIFRA]" (FIFRA section 25(b). Pursuant to this authority, EPA has exempted from the pesticide registration and requirements of FIFRA certain pesticide products if they are composed of specified active and inert ingredients which are listed and labeled according to EPA's regulations in 40 CFR 152.25(f). The exemption for minimum risk pesticides eliminates the need for the Agency to expend significant resources to regulate products that were deemed to be of minimum risk to human health and the environment, and for manufacturers and distributors to spend the resources to register such products.

As discussed in the proposed rule (Ref. 1), this action was initiated in response to a petition from Tidal Vision Products, LLC to add chitosan to the list of active ingredients allowable in minimum risk products (Refs. 2 and 3).

E. What are the estimated incremental impacts of this rule?

After reviewing the Cost Analysis that EPA prepared for the proposed rule (Ref. 4), EPA determined that the analysis presented in that document did not warranted changes for the final rule. A copy of the Cost Analysis is in the docket and is summarized in this unit.

If chitosan and chitosan salts formed from mixing with eligible active and inert

ingredients were not included in this exemption, persons seeking to manufacture or distribute pesticide products containing chitosan would be required to register those product(s) under FIFRA. This could entail generating supporting data, incurring submission costs, and paying registration fees. In addition, the petitioner could incur annual maintenance fees on the registrations. EPA's 2019 cost analysis estimates the cost savings of listing chitosan as an active ingredient that can be used in minimum risk pesticide products under 40 CFR 152.25(f) to be between $53,000 and $116,000 initially and about $3,400 per year thereafter for each pesticide product registered containing chitosan (Ref. 4). EPA has also determined that the estimated costs savings per product registered containing chitosan salts would be the same as those containing chitosan.

For EPA, this action may reduce the Agency's level-of-effort that would otherwise be spent on registering pesticide products with little risk. The impact on state regulatory costs is uncertain, as states have wide variability in how they regulate pesticide products registered by EPA and products exempt from registration under FIFRA section 25(b) (which include minimum risk pesticide products). The impact to each state will depend on how each state regulates pesticides registered by EPA versus how they regulate FIFRA section 25(b) products. States which register pesticides that are registered by EPA but not FIFRA section 25(b) products would see a reduced burden from the addition of chitosan (including chitosan salts, as specified) to the FIFRA section 25(b) list. However, since most states defray that burden through registration fees, the overall impact is expected to be negligible. Because the EPA does not review labels of FIFRA section 25(b) products, states may see an increased burden related to enforcing the conditions for labeling these products. Also, as a result of this action there may be more products seeking state registrations.

In the absence of an exemption, manufacturers may be foregoing development and production of chitosan-based products due to cost concerns. Thus, the exemption may ultimately benefit consumers who may see more of these products available at lower costs.

II. Background

A. FIFRA Section 25(b) Exemptions

As authorized by FIFRA section 25(b), EPA has exempted from the requirement of registration certain pesticide products if they are composed of specified ingredients (recognized active and inert substances which are listed in the regulations) and labeled according to EPA's regulations in 40 CFR 152.25(f). Starting in 1996, EPA exempted such products to reduce the cost and regulatory burdens on businesses and the public for pesticides posing little or no risk, and to focus the Agency's resources on pesticides that pose greater risk to humans and the environment.

B. Petition to Exempt Chitosan

On October 10, 2018, EPA received a petition from Tidal Vision Products, LLC (Ref. 2) requesting that chitosan be added to the list of active ingredients eligible for use in exempted minimum risk pesticide products under 40 CFR 152.25(f)(1). Subsequently, on April 4, 2019, EPA received an amendment to Tidal Vision Products, LLC's petition, requesting that chitosan also be added to the list of inert ingredients allowed in exempted minimum risk pesticide products under 40 CFR 152.25(f)(2) (Ref. 3).

The Agency deferred a decision on the 2019 petition regarding whether to add chitosan to the list of allowable inert ingredients, but granted the petition with respect to inclusion of chitosan as an eligible active ingredient for the minimum risk exemption.

C. EPA's Proposed Rule

On November 2, 2020, EPA issued a proposal to address the 2018 petition (Ref. 1). In the proposal, EPA stated that based on all the information available to the Agency, there are low risk concerns for human health or the environment if chitosan is intended for use as a minimum risk pesticide. For a more detailed explanation of the review that EPA conducted in support of the proposal, see Unit III. of the proposed rule (Ref. 1).

In the *Federal Register* of May 6, 2022 (Ref. 5), EPA announced the availability of and

sought public comment on two aquatic toxicity reports on chitosan salts that were submitted to the Agency by Tidal Vision Products, LLC (Refs. 6 and 7).

III. Public Comments and EPA's Responses

EPA received ten public comments on the proposed rule but did not receive any additional comments in response to the May 2022 document. This unit summarizes the comment received and the Agency's responses to those comments. The comments received included comments that raised questions about the human health and environmental impacts of chitosan, comments related to chitosan salts, comments on EPA's assessment of the impacts of the rulemaking, comments raising implementation issues related minimum risk pesticide products generally and chitosan specifically, and other general comments.

A. Chitosan Salts

1. *Comment.* Some commenters raised questions regarding chitosan salts such as chitosan hydrochloride (CAS No. 70694-72-3), chitosan acetate (CAS No. 87582-10-3), chitosan lactate (CAS No. 66267-50-3), or chitosan salicylate (CAS No. 84563-67-7). One of the commenters stated that chitosan itself is insoluble and that due to its insolubility, chitosan must first be converted into a soluble chitosan salt before it can be effectively utilized in many different industries (water treatment, drug delivery, pest control, etc.). This process involves reacting chitosan with an acid to produce a chitosan salt. The salts are water soluble and functional for a wide range of uses. The commenter stated that the salts are bioavailable to organisms and develop the ability to cause toxicity to gilled organisms at relatively low concentrations. The commenter also stated that studies have shown acute toxicity of chitosan acetate to fish at less than 1 mg/L and that fish and gilled organisms exposed to chitosan salts experience respiratory stress that can lead to death by hypoxia. The commenter recommended that EPA make clear differentiation between chitosan and chitosan salts. According to the commenter, chitosan is not equal to, nor interchangeable with chitosan acetate, chitosan lactate, and chitosan hydrochloride. Chitosan is a different chemical with a different CAS number than each chitosan salt.

2. *EPA Response.* EPA reviewed the information provided by the commenter and searched the public literature on this point. The Agency also reviewed two aquatic toxicity reports on chitosan salts submitted by Tidal Vision Products, LLC (Refs. 6 and 7). EPA announced the availability of and sought comments on both reports in May 2022 (Ref. 5) and did not receive any comments.

In addition, EPA performed an extensive literature search and data analysis for all chitosan salts with an emphasis on those created in the pesticide products currently registered with the Agency. EPA also developed an addendum to the science review in support of the addition of chitosan to the list of minimum risk pesticides contained in 40 CFR 152.25(f) (Ref. 8). In that document, EPA noted that the petition to include chitosan on the list of minimum risk pesticides specifically requests addition of chitosan with CAS No. 9012-76-4 to the list, which is the chitosan polymer produced from deacetylation of chitin, an insoluble chemical commonly referred to "dry" chitosan. Through further investigation, the Agency believes that some registered products containing 'dry' chitosan as active ingredients along with solubilizing acids as inert ingredients form chitosan salts (Ref. 8).

The Agency's overall analysis of the available data suggests that these substances are of low toxicity to humans. No risks of concern have been identified. However, EPA notes that the human health assessment database is limited both in terms of studies performed and representative chitosan salts tested.

EPA has not found any evidence that chitosan salts have adverse effects on non-target terrestrial organisms. While the form and exposure from dry chitosan used in fish feed suggests low risk to aquatic taxa, studies identified in the scientific literature indicate chitosan acetate has the potential to be highly toxic to rainbow trout. Guideline studies available in the Agency's database, on the other hand, indicate that chitosan acetate is moderately toxic to fish and aquatic invertebrates. Studies used in this assessment were selected because they reported the necessary information (e.g., LC50 values) for risk calculations and adhered to Agency guidelines.

Calculated risks quotients (RQs) based on non-target organism toxicity data and aquatic exposure modeling are below the Agency's level of concern by several orders of magnitude. Therefore, EPA is adding chitosan and any salts formed from the mixing of chitosan with minimum risk active or inert ingredients to the list of eligible active ingredients at 40 CFR 152.25(f)(1).

B. Human and Environmental Health

1. *Comments.* EPA received a comment in general support of the rulemaking, stating that the scientific evidence is clear and consistent in showing that chitosan is safe to humans and the environment. Another commenter opposed the addition of chitosan to the list of active ingredients allowed in minimum risk pesticide products, stating that that there are numerous concerns with the potential composition and purity of chitosan produced for minimum risk pesticide products as well as potential adverse effects due to significant increase in exposure. The commenter also noted that any adverse effects from the use of chitosan in minimum risk pesticide products would not be required to be reported under FIFRA section 6(a)(2). This would include adverse effects to humans, domestic animals, and the environment, such as bee kills.

2. *EPA response.* Reporting under FIFRA section 6(a)(2) is outside the scope of this rulemaking, as it applies to the minimum risk exemption in general. EPA acknowledges that the FIFRA section 6(a)(2) reporting requirement is limited to registered pesticides, and that minimum risk pesticide products, which are not registered, would not be subject to this requirement. Substances placed on the minimum risk list are not expected to present significant hazard to humans or non-target organisms. The available data do not indicate that chitosan or its salts present a significant hazard to bees or other insects.

3. *Comment.* One commenter states that a search of the Food and Drug Administration (FDA) inventory of Generally Recognized as Safe (GRAS) Notices indicates that chitosan does not have FDA GRAS status under 21 CFR 170.36. Another commenter wrote that chitosan is used in pharmaceutical manufacturing and as a supplement and the FDA has approved chitosan

as safe for use in food in drugs, and that the chemical is not considered hazardous by the Occupational Safety and Health Administration.

4. *EPA response.* While the Agency does consider whether a substance is recognized by the FDA as safe (see e.g., 61 FR 8876, March 6, 1996 (FRL-4984-8)), whether or not a substance is GRAS is not necessarily dispositive. GRAS status is initiated via a notification to the Food and Drug Administration from a company, so the lack of GRAS status may not reflect safety. (Ref. 9). In EPA's previous science review (Ref. 10), the Agency identified that a fungal based chitosan derived from *Aspergillus niger* has GRAS status. The status pertains to the specific intended conditions of use as a secondary direct food ingredient in the manufacture of alcoholic beverages. The EPA acknowledges that other forms of chitosan (e.g., chitosan derived from crustacea) do not have GRAS designations.

5. *Comment.* The commenter also noted that there may be allergenicity concerns for exempted chitosan products. Chitosan products which are currently registered by the EPA have undergone the EPA registration process and are produced by entities registered with the EPA as pesticide producing establishments. The commenter expressed a concern that if chitosan is added to the list of exempted active ingredients, products will be produced using inadequate extraction and purification processes and will contain chitosan of substandard purity and composition. According to the commenter, such products may be quite harmful to individuals with allergies. The commenter wrote that there may be little concern for allergenic response following exposure to highly purified chitosan, but that there is no control over the production and resulting level of purity for EPA exempted products.

6. *EPA response.* Allergenicity concerns were addressed in the assessment supporting the original proposed rule (Ref. 10), which discussed the manufacturing process for chitosan and some reports related to potential allergenicity. As noted in that assessment, industrially-manufactured chitosan is not likely to have allergenicity concerns provided that all animal proteins are removed during the extraction and purification process from chitin. The

manufacturing process that involves demineralization with hydrochloric acid, protein removal with sodium hydroxide and a final extraction with organic solvents is likely sufficient to remove and/or denature any proteins, fats and other contaminants of allergenic or other toxic concern. While there has been research into other methods of manufacturing chitosan, this process is understood to be the industry standard and other methods have not been shown to be viable on the scale required to produce chitosan at its current level of demand. Presence of materials (e.g., shellfish proteins) that are not listed as active or inert ingredient eligible to be used in a minimum risk pesticide product would make a product ineligible for the exemption. It is also noted that although chitosan is not a food, it has numerous food related uses and is frequently consumed as a dietary supplement.

7. *Comment.* One commenter noted that EPA's statement in the proposal stated that "no increased risk to human health or the environment is expected from chitosan," is based on current use patterns and use rates of chitosan. The commenter believes it is impossible to know what future uses may be developed. In addition, currently registered chitosan products with a relatively low percentage of active ingredient (0.25%) bear labeling which warns of moderate eye irritation. All EPA registered chitosan products have extensive First Aid Statements regarding eye and skin protection. Agricultural products bear extensive Personal Protective Equipment (PPE) requirements for applicators, mixers and loaders which include long sleeved shirt, long pants, waterproof gloves and protective eyewear. Minimum risk pesticide products are exempt from the Worker Protection Standard and they are not required to have any precautionary and first aid statements. Therefore, the commenter believes it is highly likely that there will be significant exposure if chitosan is added to the list of permitted active ingredients for minimum risk pesticide products. According to the commenter, increase in use with additional use patterns and potentially higher concentrations with unknown purity without the current precautionary and first aid label statements will result in significant exposure.

8. *EPA response.* The Agency understands that with the addition of chitosan to the

minimum risk pesticides active ingredient list, the uses and application rates could be expanded. However, EPA notes that the uses for currently registered agricultural products are extensive. The Agency has also registered products containing chitosan for antimicrobial uses to control odor causing, spoilage, and discoloration for microbes on textiles and surfaces which present additional exposure pathways that have been determined to not present risk to human health or the environment. The percentage of chitosan in end use products currently ranges from 0.05% to 85%, and chitosan is present at <5% in most products upon application. Agricultural application rates range from 0.11-2.5 lbs active ingredient (AI)/Acre for foliar sprays, 0.24-2.5 lbs AI/Acre for chemigation, and 0.11- 0.33 lbs AI/10 gallons for seed treatments based on the end-use products (EP) use sites (Ref. 8). With respect to the commenter's contention that registered chitosan products have extensive First Aid Statements regarding eye and skin protection, EPA notes that precautionary language on registered product labels is based on the acute toxicity profile of the entire EP formulation, which is the active and inert ingredients. These inert ingredients may be contributing to the toxicity profile. EPA acknowledges that an acute eye irritation study done on a 99.9% chitosan MP was moderately irritating (Tox Cat III). This could result in eye irritation due to incidental exposure (splashing) when handling the 85% undiluted end product, but not once products are diluted and being applied.

9. *Comment.* A commenter notes that there is one CAS No. for "Chitosan" listed in the petition, but that it is widely reported that this or similar materials are available in a range of varieties (e.g., different molecular weights), are often modified or made into chemical derivatives, or otherwise complexed with other materials (e.g., metal ions) to change the functional properties or to increase or change functional activity. Given that these modifications can significantly alter the functionality and by extension, the pesticidal activity, the commenter believes it is incumbent upon the EPA to consider and address how the limits or boundaries of the use of such a raw material and the possible derivations of it would be regulated and enforced as being exempt.

10. *EPA response*. The status of chitosan salts is discussed in more detail in Unit III.A. EPA notes that the listing for chitosan refers specially to poly-D-glucosamine (CAS Reg. No. 9012-76-4). The specifications that EPA is including in the regulatory text would include chitosan salts formed by solubilization with acids from the minimum risk pesticide active or inert ingredient lists and would not include other chitosan derivatives. For a more detailed discussion of molecular weight, please see the addendum to the science review in support of the addition of chitosan to the list of minimum risk pesticides contained in 40 CFR 152.25(f) (Ref. 8).

11. *Comment.* One commenter stated that chitosan's safety has not been thoroughly studied and there are still many unknowns. The commenter further stated it is not known whether chitosan is safe to take by women who are pregnant or breastfeeding and most doctors advise pregnant women to avoid products that contain it. Additionally, the commenter believes chitosan has the potential to interfere with how blood thinners work in your body.

12. *EPA response.* The risk assessments performed on chitosan and chitosan salts determined that there are no hazard concerns in humans associated with pesticidal use of chitosan. Exposure is expected to be incidental when chitosan is used as a pesticide with good agricultural practices and would not include exposure amounts that would be expected to result from intentional ingestion. Chitosan is frequently consumed as a dietary supplement, is also included as a component of drugs, and it is exempted from the requirement of a tolerance on food and feed when used in pesticide products. While there are websites that recommend against chitosan intake by pregnant women, there is no information available to the Agency to evaluate these recommendations or their scientific basis. Additionally, the Agency is not aware of any adverse developmental or reproductive toxicity effects from exposure to chitosan at doses relevant to pesticide risk assessment and did not find reports of developmental effects in an extensive search of the public literature. With respect to chitosan's interactions with anticoagulants, EPA was able to find only one study in the literature that described a possible potentiation of warfarin's effect in an 83-year-old male consuming 1,200 mg of chitosan twice

per day (Ref. 11). There are no other reported incidents of this effect in the scientific literature, and little additional information on this potential interactive effect is available.

C. Costs, Benefits, and Implementation Concerns

1. *Comment.* One commenter expressed a concern that the proposal underestimates costs associated with minimum risk pesticides, noting that numerous states are now requiring generation of additional data as a condition of state registration which obviates financial and regulatory relief described in the proposal. The commenter states that it is confusing as to why this was noted in the Cost Analysis document but was not discussed in the proposal itself. Another commenter noted that the main reason given to add chitosan, and other active ingredients, to the list of active ingredients allowed in minimum risk pesticide products is to save money associated with EPA fees established under the Pesticide Registration Improvement Extension Act (PRIA fees) and registration maintenance fees, as well as saving EPA resources that would be used reviewing and registering pesticide products of minimum concern. The commenter believes the aforementioned burden of review and registration is shifted to the states. The commenter states that currently, only nine states do not require state registration of minimum risk pesticide products. According to the commenter, the amount of time, effort and resources expended by the states for the review and registration of minimum risk pesticide products is compounded due to the lack of central EPA oversight.

2. *EPA response*. These comments are generic to the minimum risk exemption and therefore outside the scope EPA's proposal to add chitosan to the list of active ingredients allowed in minimum risk pesticide products. EPA notes that on April 8, 2021 (Ref. 12), EPA published an advanced notice of proposed rulemaking (ANPRM) that requested public comment on, among other things, modifications to the existing regulations at 40 CFR 152.25, including the exemption for minimum risk products. EPA is currently evaluating these public comments and considering potential program improvements that the Agency could propose, and EPA will consider this comment as part of that evaluation. The concerns commenters are raising could

apply equally to any of the active or inert ingredients eligible for use in minimum risk pesticide products, as well as any future ingredient. While EPA is currently evaluating potential improvements it could propose for the minimum risk pesticide program, the Agency is not considering a moratorium on adding ingredients to these lists pending completion of that effort.

EPA notes that in the Cost Analysis (Ref. 4), the Agency acknowledges that the impact on state regulatory costs is uncertain – states have wide variability in how they regulate pesticides that are registered by EPA versus FIFRA section 25(b) pesticide products. Because the Agency does not review labels of FIFRA section 25(b) products, states may see an increased burden associated with enforcing the conditions for labeling products containing chitosan. EPA also noted in that document that some states require registration of FIFRA section 25(b) products. If the Petitioner or another entity wants to sell their product in these states, they may face data generation costs similar to those that would be imposed by EPA for a national registration, potentially eliminating or reducing the savings described in the Cost Analysis. The Petitioner could avoid these costs but would forego marketing in those states.

3. *Comment.* A commenter also states that there are currently numerous registered FIFRA products containing chitosan and it is unlikely that the registrants of these products will cancel or discontinue their registrations due to the costs already incurred. The commenter believes it is unclear whether state lead agencies will register a minimum risk pesticidal product containing the same active ingredient as a FIFRA-registered product, or at least require additional testing to support the state registration. This would again incur additional costs or burden not adequately captured in the proposed rule.

4. *EPA response.* This rule will not affect the status of already registered products or create additional costs for already registered products. Additionally, state requirements for additional testing are not affected by this rule.

D. Miscellaneous Comments

1. *Comment.* One commenter noted concerns regarding inappropriate use and claims for

the control of bacteria and mold. The commenter states that chitosan is currently registered as an antimicrobial pesticide active ingredient to inhibit growth of bacteria, mold, mildew, and fungi. The commenter is concerned that exempt products will be produced with false and misleading statements regarding efficacy against bacteria or for mold remediation.

2. *EPA response*. Per the requirements of 40 CFR 152.25(f) minimum risk pesticide are subject to certain restrictions. Products that do not meet these requirements would not be eligible for the exemption. One such restriction prohibits minimum risk products from bearing claims to control any microorganism that pose a threat to human health. However, some types of claims regarding microorganisms can meet the conditions of the minimum risk exemption. An example would be an antimicrobial pesticide product that bears a claim to control microorganisms of economic or aesthetic significance, and the presence of the microorganism would not normally lead to infection or disease in humans.

3. *Comment.* One commenter expressed a concern regarding the potential for false or misleading claims on chitosan products, should chitosan be added the active ingredient list for minimum risk pesticides. The commenter writes that chitosan used in pesticide products is not a naturally occurring substance and must be chemically derived. Therefore, industrially manufactured chitosan would not be considered "organic" or "natural" and such claims would be false and misleading.

4. *EPA response.* This comment is outside the scope EPA's proposal to add chitosan to the list of active ingredients allowed in minimum risk pesticide products. The commenter's concern could apply equally to any minimum risk pesticide product and is not specific to those containing chitosan. By way of background, EPA does note that per the requirements of 40 CFR 152.25(f)(3)(iv) the labels of minimum risk product cannot include any false or misleading statements, including those listed in 40 CFR 156.10(a)(5)(i) through (viii). However, EPA acknowledges that 40 CFR 156.10(a)(5)(x) which prohibits "[n]on-numerical and/or comparative statements on the safety of the product, including but not limited to: (A) 'Contains all natural

ingredients'; (B) 'Among the least toxic chemicals known' [or] (C) 'Pollution approved'" does not directly apply to minimum risk products, but EPA notes that 40 CFR 152.25(f)(3)(iv) contains a general prohibition on false or misleading statements.

5. *Comment.* One commenter writes that given that chitosan is currently on the FIFRA inert ingredients list and is approved for non-food use, it is unclear how a registrant or state lead agency would determine whether chitosan is acting as an active ingredient or inert. This is an area that the states lead agencies have expressed as particularly challenging with inert ingredients and the proposal does not address this consideration. If the material is considered exempt from FIFRA regulation only as an active ingredient and not as an inert ingredient, then this question carries significant importance in determination of whether a product containing it is considered exempt or not from FIFRA regulation.

6. *EPA response.* The commenter is correct that the active ingredient and inert ingredient lists are not interchangeable. Unless the ingredient appears on both lists, it can only be used based on the list it appears on. So, in this case, chitosan may only be used in minimum risk pesticide products as an active ingredient. The regulations at 40 CFR 152.3 define an active ingredient to mean, in relevant part, "any substance . . . that will prevent, destroy, repel or mitigate any pest, or that functions as a plant regulator, desiccant, or defoliant . . . ." An inert ingredient means "any substance . . . other than an active ingredient, which is intentionally included in a pesticide product . . . ." Accordingly, chitosan in minimum risk pesticide products must prevent, destroy, repel or mitigate a pest, or function as a plant regulator, desiccant, or defoliant.

7. *Comment.* One commenter suggested that adding chitosan to the list of minimum risk active ingredients would have the effect of switching the burden to the states. The commenter believes that maintaining EPA's registration and central oversight would be the best option. The commenter suggested the creation of separate lower fee PRIA categories to review and register chitosan and other minimum risk pesticide products.

8. *EPA response.* This comment raises generic issues with the Minimum Risk Pesticide Program that go beyond the specific issues raised in this rulemaking, namely the addition of chitosan and chitosan salts to the list of active ingredients. As previously noted, EPA published an ANPRM that requested public comment on, amongst other things, modifications to the existing regulations at 40 CFR 152.25, including the exemption for minimum risk products (Ref. 12). EPA is currently evaluating these public comments and considering potential program improvements that the Agency could propose, and EPA will consider this comment as part of that evaluation.

9. *Comment.* The commenter states that some agricultural and commercial pesticide users are hesitant to use products that are not EPA registered because there is a question as to whether the products are compliant with all exemption criteria. The commenter states that the lack of an easily identifiable EPA Registration Number and associated product label is very problematic because it is difficult to ascertain whether a product is legal and compliant.

10. *EPA response.* This comment also raises generic issues with the Minimum Risk Pesticide Program that go beyond the specific issues raised in this rulemaking, namely the addition of chitosan and chitosan salts to the list of active ingredients. As previously noted, EPA is currently evaluating these public comments on the ANPRM (Ref. 12) and considering potential program improvements that the Agency could propose, and EPA will consider this comment as part of that evaluation.

11. *Comment.* One commenter notes that minimum risk pesticide products are not covered under the EPA provisions which protect confidential business information (CBI).

12. *EPA response*. In general, EPA would not routinely be in possession of confidential business information on minimum risk pesticide products because such products are not reported to EPA. Regardless, the Agency disagrees with the commenter that minimum risk pesticide products are not protected by the business confidentiality provisions in FIFRA section. Exemption of pesticides under section 25(b) pertains to “the requirements of this subchapter

[FIFRA]". That does not leave companies bereft of the confidentiality protections in FIFRA section 10.

13. *Comment.* Another commenter suggested that EPA correct an apparent spelling error on its website for "Inert Ingredients Eligible for FIFRA 25(b) Pesticide Products." On this website list, the name for CAS No. 6132-04-3 is listed as Trisodium citrate dehydrate (as label display name) and Citric acid, trisodium salt, dehydrate (as the chemical name). However, in 40 CFR 180.950(e) the CAS No. 6132-04-3 is associated with Citric acid, trisodium salt, dihydrate. The comment suggests that the "dehydrate" on the website be changed to be "dihydrate" in conformance with the regulations.

14. *EPA response.* This comment is outside of the scope of the proposed rulemaking. However, in reviewing the comment, EPA has determined the commenter is correct in that there is a typographical error and that the correct label display name associated with CAS No. 6132-04-3 should be "Trisodium citrate dihydrate". EPA notes that the website the commenter is referring to merely duplicates the list of inert ingredients codified at 40 CFR 152.25(f)(2)(iv), where CAS No. 6132-04-3 is associated with the label display name "Trisodium citrate dehydrate" and the chemical name "Citric acid, trisodium salt, dehydrate." EPA did not propose to make any change to the entry for this chemical, but because this is purely a typographical error, EPA is correcting that error in this action.

IV. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. Pesticides; Proposal to Add Chitosan to the List of Active Ingredients Permitted in

Exempted Minimum Risk Pesticide Products; Proposed Rule. *Federal Register*. 85 FR 69307, November 2, 2020 (FRL-10009-24).

2. Tidal Vision Products, LLC. Petition to list the material Chitosan CAS# 9012-76-4 on the U.S. EPA FIFRA Minimum Risk List 40 CFR 152.25(f). October 10, 2018.

3. Tidal Vision Products, LLC. Amendment to the Petition to add Chitosan to the Minimum Risk Pesticide Inert Ingredient List at the same time as adding Chitosan to the Minimum Risk Pesticide Active Ingredient List; Re: Petition to list the material Chitosan CAS# 9012-76-4 on the U.S. EPA FIFRA Minimum Risk Pesticide List 40 CFR 152.25(f). April 4, 2019.

4. EPA. Cost Analysis of the Proposed Modification to the Minimum Risk Pesticide Listing Program. Prepared by Biological and Economic Analysis Division, Office of Pesticide Programs. July 2020.

5. EPA. Pesticides; Proposal to Add Chitosan to the List of Active Ingredients Permitted in Exempted Minimum Risk Pesticide Products; Notice of Data Availability on Chitosan and Chitosan Salts; Notification of data availability. *Federal Register*. 87 FR 27059, May 6, 2022 (FRL-7542-03-OCSPP).

6. Tidal Vision USA. Aquatic Toxicology Report by Eurofins Environmental Testing Test America. Lab I.D. No. B4345. Report Date: June 17, 2019. EPA Master Record Identification (MRID) 51861901.

7. Tidal Vision USA. Aquatic Toxicology Report by Eurofins Environmental Testing Test America. Lab I.D. No. B4421. Report Date: August 28, 2019. EPA Master Record Identification (MRID) 51861902.

8. EPA. Addendum to the science review in support of the addition of chitosan (Poly-D-Glucosamine) to the list of minimum risk pesticides (MRPs) contained in 40 CFR 152.25(f). September 2022.

9. FDA. Intended for Use in Human Food or Animal Food on the Basis of the Generally Recognized as Safe (GRAS) Provision of the Federal Food, Drug, and Cosmetic Act: Guidance

for Industry. November 2017. Available at *https://www.fda.gov/media/109117/download*.

10. EPA. Science review in support of the addition of Chitosan (Poly-D-Glucosamine) to the list of minimum risk pesticides (MRPs) contained in 40 CFR 152.25(f). August 23, 2019.

11. Huang, S. S., Sung, S. H., & Chiang, C. E. (2007). Chitosan potentiation of warfarin effect. The Annals of Pharmacotherapy, 41(11), 1912–1914. November 1, 2007. Available at https://doi.org/10.1345/aph.1K173.

12. EPA. Pesticides; Modification to the Minimum Risk Pesticide Listing Program and Other Exemptions Under FIFRA Section 25(b); *Federal Register*. 86 FR 18232, April 8, 2021 (FRL-10016-29).

V. FIFRA Review Requirements

In accordance with FIFRA section 25(a), EPA submitted a draft of this final rule to the United States Department of Agriculture (USDA) and the FIFRA Scientific Advisory Panel (SAP) for review. A draft of the rule was also submitted to the appropriate Congressional Committees.

USDA responded without comments on October 7, 2022. The FIFRA SAP waived its scientific review of this rule on October 13, 2022, because the rule does not contain scientific issues that warrant review by the Panel.

VI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders*.

A. Executive Order 12866: Regulatory Planning and Review; and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act (PRA)

This action does not impose any new information collection requirements that would require additional review or approval by OMB under the PRA, 44 U.S.C. 3501 *et seq*. The information collection activities required under the exemption are covered by an existing Information Collection Request (ICR), entitled "Labeling Requirements for Certain Minimum Risk Pesticides under FIFRA Section 25(b)," approved under OMB Control No. 2070-0187 and identified by EPA ICR No. 2475. The existing ICR estimates the burden of displaying mandatory active and inert ingredient and producer information on the labels of minimum risk pesticide products. To maintain exemption status, an exempt pesticide product must display the following information on its label; the label display name and the percentage (by weight) of all active ingredients, the label display name of all inert ingredients, and the name of the producer or the company for whom the product was produced, along with the producer/company's contact information. Labels provide important regulatory information for the Federal, State, and Tribal authorities that regulate or enforce minimum risk pesticide products.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA, 5 U.S.C. 601 *et seq*. In making this determination, EPA concludes that the impact of concern for this rule is any significant adverse economic impact on small entities, and the Agency is certifying that this rule will not have a significant economic impact on a substantial number of small entities because the rule relieves regulatory burden. This action adds substances to the list of active ingredients allowed in exempted minimum risk pesticide products reduces existing regulatory burden and will not have a significant economic impact on a substantial number of small entities. The cost savings are summarized in Unit I.E. We have therefore concluded that this action will relieve regulatory burden for all directly regulated small entities.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate as described in UMRA, 2 U.S.C.

1531-1538, and does not significantly or uniquely affect small governments. This action imposes no enforceable duty on any state, local, or Tribal governments because there are no known instances where such governments currently produce any pesticides such that they would be subject to this rulemaking. Accordingly, this action is not subject to the requirements of UMRA.

E. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). It will not have substantial direct effects on the states, on the relationship between the National Government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This action does not have Tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). This action will not have any effect on Tribal governments, on the relationship between the Federal Government and the Indian tribes, or the distribution of power and responsibilities between the Federal Government and Indian tribes. Currently, there are no known instances where a Tribal government is the producer of a minimum risk pesticide product exempt from regulation.

G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of "covered regulatory action" in section 2–202 of the Executive order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001),

because it is not a significant regulatory action under Executive Order 12866 and because this action has not otherwise been designated as a significant energy action by the Administrator of the Office of Information and Regulatory Affairs.

I. National Technology Transfer and Advancement Act (NTTAA)

This action does not involve technical standards as specified in NTTAA section 12(d), 15 U.S.C. 272 note.

J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

This action does not entail special consideration of environmental justice issues as delineated by Executive Order 12898 (59 FR 7629, February 16, 1994) and Executive Order 14008 (86 FR 7619, January 27, 2021), because this rule does not establish an environmental health or safety standard.

K. Congressional Review Act (CRA)

This action is subject to the CRA, 5 U.S.C. 801 *et seq*., and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 152

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 21, 2022.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

Therefore, for the reasons stated in the preamble, 40 CFR chapter I is amended as follows:

PART 152 – PESTICIDE REGISTRATION AND CLASSIFICATION PROCEDURES

1. The authority citation for 40 CFR part 152 continues to read as follows:

Authority: 7 U.S.C. 136–136y; Subpart U is also issued under 31 U.S.C. 9701.

2. Amend § 152.25 by:

a. Adding alphabetically the entry "Chitosan" to table 1 to paragraph (f)(1); and

b. Removing the entry for "Trisodium citrate dehydrate" and adding in its place the entry "Trisodium citrate dihydrate" in table 2 to paragraph (f)(2).

The addition and revision read as follows:

§ 152.25 Exemptions for pesticides of a character not requiring FIFRA regulation.

* * * * *

(f) * * *

(1) * * *

Table 1 – Active Ingredients Permitted in Exempted Minimum Risk Pesticide Products

Label display name	Chemical name	Specifications	CAS No.
* * * * * * *			
Chitosan	Poly-D-glucosamine	Includes chitosan salts (consisting solely of those salts that can be formed with the acids listed in this table or table 2 to paragraph (f)(2) of this section).	9012-76-4
* * * * * * *			

(2) * * *

Table 2 – Inert Ingredients Permitted in Minimum Risk Pesticide Products

Label display name	Chemical name	CAS No.
* * * * * * *		
Trisodium citrate dihydrate	Citric acid, trisodium salt, dihydrate	6132-04-3
* * * * * * *		

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